EMA/436421/2019

Record of data processing activity for handling of reports of alleged improprieties from external sources (public)

1.	Last update of this record, version number:	17 December 2019, version 1
2.	Reference number:	P6
3.	Name and contact details of controller:	Controller: European Medicines Agency (EMA) Contact: Head of Inspections, Human Medicines Pharmacovigilance and Committees Division, EMA Contact: reporting@ema.europa.eu
4.	Name and contact details of DPO:	Contact: dataprotection@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	N/A
6.	Name and contact details of processor (where applicable)	N/A
7.	Purpose of the processing	To gather and handle information from external sources disclosing alleged improprieties concerning EMA activities related to the authorisation, supervision and maintenance of human and veterinary medicinal products in accordance with EMA's policy 0072; to assess the allegations and decide on the steps and/or actions to take as part of the obligations of the EMA as medicinal products regulator. A dedicated email box, reporting@ema.europa.eu, is available to external sources to report alleged improprieties, which is mentioned on the dedicated webpage on the EMA website (link). Policy 0072 on handling of information from external sources disclosing alleged improprieties concerning EMA activities

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

		related to the authorisation, supervision and maintenance of human and veterinary medicinal products: (Path: About us / How we work / Handling reports of alleged improprieties – Link: https://www.ema.europa.eu/en/documents/other/policy-72-european-medicines-agency-policy-handling-information-external-sources-disclosing-alleged_en.pdf)
8.	Description of categories of persons whose data EMA processes and list of data categories	EMA processes the following data from an external source disclosing alleged improprieties concerning EMA activities related to the authorisation, supervision and maintenance of human and veterinary medicinal products: • first name and surname of the source, email address and organisation of the source. • any personal data included in the report and related documentation. The report and related documentation include the following: • area of suspected GxP non-compliance; • description and context of the suspected impropriety; • concerned pharmaceutical company and/or medicinal product; • any additional information available to the external source. EMA maintains an overview containing summary data on the reports from external sources received and handled by the EMA, which includes: • case number and date of receipt; • date of acknowledgment of receipt; • name and organisation of the source; • indication if contact details are available and if the source wishes to keep his contact details confidential; • general description of the issue/allegations; • concerned medicinal product; • concerned company; • summary of steps and/or actions taken; • outcome of the assessment.
9.	Time limit for keeping the data	Reports of alleged improprieties from external sources are kept after closure of the case for:

		• 30 years after withdrawal of the marketing authorisation of the product: if the allegation falls within EMA's remit to examine the allegation; • 12 months: if the allegation does not fall within EMA's remit to examine the allegation, but the allegation is transferred to the concerned Member State or competent authority or if the case was closed after triage with no initial evaluation or after initial evaluation with no assessment. An overview containing summary data on the reports received and handled by the EMA is kept for administrative purposes. Personal data is anonymised at the end of the retention period.
10.	Recipients of the data	Only a limited number of EMA staff is handling reports of alleged improprieties from external sources. Additional EMA staff members can be involved, but only on a case-by-case and need-to-know basis. The allegations of improprieties may be passed to an EU institution or body (for example, European Anti-Fraud Office, European Ombudsman, Internal Audit Service of the European Commission, European Court of Auditors), EU national or non-EU competent authority for further assessment. This transfer will include personal data where the EMA does not have the competence to examine the allegations. In exceptional circumstances, the Agency may also disclose personal data in the event of any subsequent legal proceedings and/or due to a court order or if it is established that the allegations are malicious and a false statement has been made.
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	Certain categories of data (i.e. information on allegations of improprieties) may be shared with third country regulatory authorities and international organisations responsible for medicinal products based on mutual cooperation agreements. This will allow them to assess the information in case it falls under their remit.
12.	General description of security measures, where possible.	All information and documentation regarding reports of alleged improprieties from external sources received and handled by EMA in accordance with policy 0072, as well as the overview of reports, are kept in a dedicated folder in the Agency's document management system with restricted access. Access is limited to a limited number of EMA staff. The same applies for access to the dedicated e-mail box of reporting@ema.europa.eu. Original paper documents are stored securely in a locked cabinet or secure room in the offices of the Agency.

13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement:	A privacy statement is included in the template to report an allegation concerning an impropriety in an area of EMA's responsibility, which is available on the EMA website. (Path: About us / How we work/ Handling reports of alleged improprieties – link: https://www.ema.europa.eu/documents/template-form/template-report-allegation-concerning-impropriety-area-emas-responsibility-authorisation-supervision_en.doc)